

**REMARKS**

Claims 1-3 remain in this application.

In order to place the present application in condition for allowance, claim 1 has been amended to recite a bandage providing a cooling effect to a user, comprising: (i) a flexible and leak proof cold pack container having a first end and a second end; (ii) a first bandage support member integrally attached to the first end of said cold pack container; (iii) a second bandage support member integrally attached to the second end of said cold pack container; (iv) at least one chemical agent and at least one solution collectively disposed within said cold pack container, which, when mixed, undergo an endothermic reaction; (v) means for separating said agent and said solution within at least one chamber within said cold pack container of said bandage, at least one portion of said separating means being easily broken or ruptured so that said agent and said solution may be mixed; (vi) a first skin-adhesive portion located on said first bandage support member for affixing the bandage to the body of said user; (vii) a second skin-adhesive portion located on said second bandage support member for affixing the bandage to the body of said user; and (viii) a sterile portion adapted for contact with the area of the body to be covered by said bandage. Each of the foregoing amendments is clearly supported by the original specification. Consequently, no new matter has been added.

Applicant's invention, as recited by claims 1-3, as amended, provides a bandage with cooling capabilities for a user that includes bandage support members and a flexible and leak proof cold pack member integrally attached and positioned between the support members. The cold pack member includes a chemical which endothermically reacts with

water, positioned adjacent to but separate from a water source inside a common package, to instantly cool the cold pack member upon activation. The cold pack member further comprises a sterile pad member positioned on the bottom side of the bandage, which may include an antibiotic, anesthetic, antipyretic, burn medicament, or combinations thereof.

**Claim Rejections – 35 USC § 112**

Claim 1 was rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

The Examiner stated that previous claim 1 contained subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner stated that applicant's original specification did not provide support for the term "permanently". The Examiner indicated that the specification did recite that the cold pack can be "attached" or "integrally attached" to the bandage support member.

Applicant respectfully traverses this argument. The drawings and specification as originally filed disclose first and second bandage support members being permanently attached to the cold pack member. See page 2 of the specification as originally filed which states that: "cold pack member 20 can be integrally attached or sealed to two bandage support members 30, each one attached to either side of cold pack member 20". It is submitted that when an item is "sealed" to another item, it is permanently attached to the item. Nonetheless, in order to advance prosecution of this application, claim 1 has

been amended to replace the word "permanently" with the word "integrally". Applicant submits that claim 1, as amended, is in compliance with 35 USC 112, second paragraph.

Accordingly, reconsideration of the rejection of claim 1 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is respectfully requested.

**Claim Rejections – 35 USC § 103**

Claims 1 and 3 were rejected under 35 USC 103(a) as being unpatentable over Pyrozyk et al. (USP 5,431,622) in view of Caillouette (USP 3,643,665).

Pyrozyk et al. discloses a thermal bandage apparatus for simultaneously dressing and thermally treating a wounded bodily area. The thermal bandage apparatus includes a fluid absorbent member having a wound-contacting surface for absorbing bodily fluids produced by an open wound. A holding means adjacent and connected to the fluid absorbent member holds a thermal medium against the fluid absorbent member such that heat is transferred between the thermal medium and the open wound by thermal conduction through the fluid absorbent member. There is also disclosed an arrangement for providing a continuous supply of heat or cold to a wound.

Caillouette discloses a therapeutic pack containing chemicals that produce a temperature-changing chemical reaction, e.g. endothermic or exothermic. The chemical components for the reaction are held spaced apart within a bag by a fracturable means, e.g. a diaphragm. The bag incorporates an insulation cover, e.g. minutely expanded polystyrene paper and aluminum foil, various portions of

which may be selectively removed to provide an effective heat-transfer path of a predetermined size, to accomplish the desired therapeutic treatment.

The Examiner has indicated that it would have been an obvious design choice to one having ordinary skill in the art to modify the thermal dressing of Pyrozyk et al. substituting its thermal pack for the thermal pack of Caillouette since the applicant has not stated that the disclosed thermal pack of the instant invention solves a particular problem. (Applicant respectfully submits that the thermal dressing of Pyrozyk et al. does not include a thermal pack, but instead includes a pocket for insertion of a thermal pack.)

Applicant respectfully traverses the Examiner's rejection of claims 1 and 3 over Pyrozyk et al. in view of Caillouette. It is submitted that Pyrozyk et al., taken alone or in view of Caillouette, does not disclose or suggest each element of claims 1 and 3, as amended. MPEP 2143.03 states that in order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.Cir. 1988).

Clearly, the suggested combination of Pyrozyk et al. in view of Caillouette does not teach or suggest a bandage that provides a cooling effect to a user, comprising: (i) a flexible and leak proof cold pack container having a first end and a second end; (ii) a first

bandage support member integrally attached to the first end of said cold pack container;  
and (iii) a second bandage support member integrally attached to the second end of said  
cold pack container, as called for by present claims 1 and 3. Because the cold pack  
container defined by present claims 1-3 is integrally attached to the first and second  
bandage support members, it is easier to use and much more reliable in operation than  
any device constructed in light of the combined teachings of Pyrozyk et al. and  
Caillouette.

It is submitted that any bandage constructed in view of the Pyrozyk et al.  
disclosure, taken in view of Caillouette, would include an interior space that is accessed by  
a slit, thereby forming a pocket. See col. 2, lines 42-60. The Examiner has suggested  
combining the bandage of Pyrozyk et al. with the cold pack of Caillouette. During use of  
any bandage constructed in light of the combined teachings of Pyrozyk et al. and  
Caillouette, a user must perform a two-step process: firstly, the user must locate a  
separate cold packet (i.e. the cold pack disclosed by Caillouette), and secondly, the user  
must insert the cold pack into the pocket of the bandage. By way of contrast, the bandage  
disclosed by present claims 1-3 is a single-piece unit, wherein the cold pack is integrally  
attached to the first and second bandage members.

Several disadvantages are inherent with the thermal bandage disclosed by  
Pyrozyk et al. in view of Caillouette. Such disadvantages include, *inter alia*, the  
following: (i) valuable time is wasted searching for the separate cold pack to be inserted  
into the bandage having a pocket, whereas the bandage of present claims 1-3 includes the  
cold pack/ bandage as a single unit; (ii) during movement of the user's body, especially if  
the bandage is placed on such bodily extremities as the arms and/or legs, the cold pack of

the bandage disclosed by the combined teachings of Pyrozyk et al. and Caillouette will be prone to movement out of the pocket and possible expulsion from the pocket of the bandage; and (iii) the user will experience difficulty when inserting a properly-sized cold pack into the pocket of the bandage; that is, the size of the cold pack must approximate that of the pocket for a tight fit, which could lead to a tearing of the cold pack during its insertion (because of the close-fit tolerance) and possible leaking of the cold solution therewithin.

It is respectfully submitted that the combined teachings of Pyrozyk et al. in view of Caillouette fail to disclose or suggest every element of claims 1 and 3, as amended. Significantly, nowhere does Pyrozyk et al. disclose or suggest that a cold pack be integrally attached to the bandage. Instead, Pyrozyk et al. requires the use of a separate cold pack that is inserted into a pocket on the bandage. Similarly, nowhere does Caillouette disclose or suggest the presence of bandage support members that are integrally attached to its cold pack. Finally, the combined teachings of Pyrozyk et al. and Caillouette do not disclose or suggest a cold pack that is integrally attached to first and second bandage support members at both its ends, respectively. Instead, because the device suggested by the combination of the above-cited references discloses a cold pack that can be removed from the pocket and disassociated from the bandage at any time, it is respectfully submitted that present claims 1 and 3 are patentable over Pyrozyk et al. in view of Caillouette.

In the latest Office Action, the Examiner has admitted that Pyrozyk et al. fail to teach that the bandage support members are permanently attached to the thermal pack; instead, Pyrozyk et al. disclose a pocket having a closable flap for maintaining the

thermal pack within the bandage. The Examiner contends that one having ordinary skill in the art would have found it obvious to permanently secure the flap by use of glue or stitching, in order to ensure that the thermal pack will not come out of the pocket.

Applicant respectfully traverses this argument. MPEP 2143.01(VI) states that the proposed modification cannot change the principle of operation of a reference – “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious”. Here, the Examiner proposes to modify the Pyrozyk et al. bandage by permanently securing flap 35, which covers the slit 32 that provides access to the pocket 34, in order to ensure that the thermal pack will not come out of the pocket. Applicant respectfully submits that this proposed modification would change the principle of operation of the Pyrozyk et al. device. Namely, the Pyrozyk bandage was designed to operate as follows: (i) the bandage is shipped in a sterile plastic wrap package; (ii) the user removes the plastic packaging; (iii) the user inserts a preheated or precooled hot/cold pack into the pocket; (iv) the user can access the pocket through the slit to permit periodic replacement of the thermal medium without requiring that the fluid absorbent member be removed from the wound. See especially Pyrozyk et al. col. 7, lines 59-62. If the flap of the pocket was permanently secured by glue or stitching, the pocket could not be accessed, and the thermal medium could not be periodically replaced. Therefore, if the Pyrozyk et al. device was modified as suggested by the Examiner, the principle of operation of the device would change from how it was specifically designed to operate. The proposed modification would further render the Pyrozyk et al. device unsatisfactory in its purpose

of providing a bandage wherein the thermal medium could be accessed and periodically replaced. See MPEP § 2143.01(V).

Furthermore, even if the modification of the Pyrozyk et al. device was accomplished, it still would not include all of the structural limitations, as particularly arranged, which are called for by claim 1, as amended. Namely, present claim 1 requires that first and second bandage support members be integrally attached to the first and second end of the cold pack, itself. On the other hand, as modified, the first and second support straps of the Pyrozyk et al. device are not integrally attached to the thermal medium pack. Instead, the first and second support straps are integrally attached to the pocket (that houses the thermal medium pack), not the thermal medium pack, itself. Because the thermal medium pack of the modified Pyrzyk et al. device is not secured to the bandage itself, it is prone to shift about inside the pocket and become twisted or folded; therefore, not laying flat next to the patient's skin. If the thermal medium pack was not flat against the skin, then the heating and/or cooling effect would not be uniform, which is problematic. The bandage called for by present claim 1, by comparison, allows a safe and secure positioning of the cold pack uniformly along side the skin of the patient. Because the support band members are integrally attached to the ends of the cold pack, there is no risk of the cold pack shifting, twisting, or folding over itself once the bandage is secured to the patient's skin.

Accordingly, reconsideration of the rejection of claims 1 and 3 under 35 USC 103(a) as being unpatentable over Pyrozyk et al. in view of Caillouette is respectfully requested.

Claim 2 was rejected under 35 USC 103(a) as being unpatentable over Pyrozyk et al. in view of Caillouette, and further in view of Keedwell (USP 3,900,027).

Keedwell discloses a process for making integral absorbent pad bandages from nonwoven thermoplastic fibrous sheet material, compressing the sheet in selected portions to reduce thickness and porosity and delimit an absorbent pad portion having a greater thickness. The resulting sheet material has a plurality of juxtaposed integral absorbent pad bandages, which can be cut off to obtain individual bandages. The individual bandages are in one piece, and can have adhesive applied thereto if desired.

It is submitted that claim 1 patentably defines over Pyrozyk et al. in view of Caillouette, and further in view of Keedwell, since the proposed combination of the references does not disclose nor suggest a cold pack container integrally attached to first and second bandage support members as called for by present claim 1. Because claim 2 depends from independent claim 1, it is submitted that claim 2 is patentable over the cited references for the very same reasons.

Accordingly, reconsideration of the rejection of claim 2 under 35 USC 103(a) as being unpatentable over the combination of Pyrozyk et al., Caillouette, and Keedwell is respectfully requested.

**CONCLUSION**

In view of the amendments to the claims and the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the Final Rejection, entry of this amendment, and allowance of claims 1-3, as amended, are earnestly solicited.

Respectfully submitted,  
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